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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,484	01/17/2006	Nai-Kong V. Cheung	639-C-PCT-US	2140
7590 08/11/2008 Albert Wai Kit Chan Law Offices of Albert Wai Kit Chan World Plaza Suite 604 141 07 20th Avenue Whitestone, NY 11357			EXAMINER OLSON, ERIC	
			ART UNIT 1623	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/565,484	Applicant(s) CHEUNG, NAI-KONG V.	
	Examiner Eric S. Olson	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

This office action is a response to applicant's amendment and arguments submitted May 13, 2008 wherein claims 1-13 are cancelled and new claims 14-29 are introduced. This application is a national stage application of PCT/US04/23099, filed July 16, 2004, which is a continuation in part of US application 10/621027, filed July 16, 2003, currently allowed, which is a continuation in part of international application PCT/US02/01276, filed January 15, 2002, which claims benefit of provisional application 60/261911, filed January 16, 2001.

Claims 14-29 pending in this application.

Claims 14-29 as amended are examined on the merits herein.

Applicant's amendment, submitted May 13, 2008, with respect to the rejection of instant claims 5, 11, and 12 under 35 USC 112, first paragraph, for lacking enablement for compositions comprising any anticancer antibody whatsoever, has been fully considered and found to be persuasive to remove the rejection as the rejected claims are cancelled and the new claims limit the scope to certain specific anticancer antibodies. Therefore the rejection is withdrawn.

Applicant's amendment, submitted May 13, 2008, with respect to the rejection of instant claims 1, 2, 5, and 9 under 35 USC 112, first paragraph, for lacking enablement for compositions comprising any chemotherapeutic agent whatsoever, has been fully

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considered and found to be persuasive to remove the rejection as the rejected claims are cancelled. Therefore the rejection is withdrawn.

Applicant's amendment, submitted May 13, 2008, with respect to the rejection of instant claims 1-13 under 35 USC 102(b) or 103(a) as being anticipated by or obvious over Yan et al., has been fully considered and found to be persuasive to remove the rejection as the rejected claims have been cancelled. Therefore the rejection is withdrawn.

Applicant's amendment, submitted May 13, 2008, with respect to the rejection of instant claims 1-13 under 35 USC 102(b) or 103(a) as being anticipated by or obvious over Herlyn et al., has been fully considered and found to be persuasive to remove the rejection as the rejected claims have been cancelled and the new claims require side chains having two or more saccharide units with beta 1,3 linkages, which excludes lentinan. Therefore the rejection is withdrawn.

Applicant's amendment, submitted May 13, 2008, with respect to the rejection of instant claims 1-13 under 35 USC 102(b) or 103(a) as being anticipated by or obvious over Suzuki et al., has been fully considered and found to be persuasive to remove the rejection as the rejected claims have been cancelled and the new claims require side chains having two or more saccharide units with beta 1,3 linkages, which excludes lentinan. Therefore the rejection is withdrawn.

Applicant's amendment, submitted May 13, 2008, with respect to the rejection of instant claims 1-7 and 9 under 35 USC 102(b) or 103(a) as being anticipated by or obvious over Jamas et al., has been fully considered and found to be persuasive to remove the rejection as the rejected claims have been cancelled and the new claims require an antitumor antibody. Therefore the rejection is withdrawn.

Applicant's amendment, submitted May 13, 2008, with respect to the rejection of instant claims 1-13 under the doctrine of obviousness-type double patenting for claiming the same invention as claim 193 of US application 10/621027, has been fully considered and found to be persuasive to remove the rejection as the rejected claims have been cancelled and the new claims require a specific structure for the beta glucan not found in 10/621027. Therefore the rejection is withdrawn.

Applicant's amendment, submitted May 13, 2008, with respect to the rejection of instant claims 1, 3, and 8 under the doctrine of obviousness-type double patenting for claiming the same invention as claim 11 of US application 11/334763, has been fully considered and found to be persuasive to remove the rejection as the rejected claims have been cancelled and the new claims require a composition further comprising an antibody. Therefore the rejection is withdrawn.

Applicant's amendment, submitted May 13, 2008, necessitates the following new grounds of rejection:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims recite chemical structures having variables m and n which are not defined in the claims or the specification. In the absence of any definition, one skilled in the art could not tell what values these variables could take, rendering the claims indefinite.

Because Applicant's amendment necessitated this new ground of rejection the rejection is made **FINAL**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yan et al. (Reference of record in previous action) in view of Donzis et al. (US patent 5519009, cited in PTO-892)

Yan et al. discloses a yeast-derived beta-glucan composition (denoted as SZP_g) capable of producing a synergistic complement-mediated antitumor effect in a mouse xenograft model of breast cancer (p. 304, right column) in combination with antitumor antibodies. (p. 3048, left column and figure 3) The beta-glucan has a 1,3-linked backbone and is branched with 1,6-linked side chains, (p. 3045, left column, first paragraph) and is obtained from yeast. (zymosan) It has a molecular weight of about 10000 kDa. (p. 3046, left column, last paragraph) On p. 11, lines 9-12 of the instant specification, “high molecular weight” is defines as being at least 10000 **daltons**. Therefore the SZP of Yan et al. is high molecular weight as described in the instant claims. The structures of claims 18 and 26 are essentially the same structures as those described by Yan et al., namely a beta 1-3 glucan backbone with 1,3 glucan side chains attached by 1,6 linkages, and the two glucans are reasonably expected to have the same biological effects by virtue of their identical structure. The combination therapy led to a synergistic effect producing more than additive results in the mice. It is explained that the normal antitumor effect of beta-glucans is only present in specific strains of mice having appropriate antibodies toward the tumor, and that the addition of exogenous antitumor antibodies can restore this activity in cases in which beta-glucan monotherapy is ineffective. (p. 3050, under the heading **Discussion**) Anti-GD2 antibodies are cited as a specific example. (p. 3050, right column, first paragraph) Note that the claimed composition is described in the base claim 1 as a composition “comprising an appropriate amount of carbohydrates.” While dependent claims such as 5, 8, and 11-13 define the substance that can be enhanced by the beta-glucan, these

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claims are worded in such a way that they do not actually require the substance to be present in the composition, so long as the composition could theoretically enhance said substance if they were co-administered. Therefore the zymosan polysaccharide described by Yan et al. is identical to the carbohydrate described in the instant claims. Any properties exhibited by or benefits provided the composition are inherent and are not given patentable weight over the prior art. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties Applicant discloses and/or claims are necessarily present. See *In re Spada*, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. Yan et al. does not disclose a composition containing both a beta glucan and an antibody.

It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare a pharmaceutical composition comprising both a beta-glucan and one of the antibodies of Yan et al. One of ordinary skill in the art would have been motivated to produce a pharmaceutical composition comprising a beta-glucan and an antibody because the method of Yan et al. comprises concurrently administering both of these active ingredients to a subject. One of ordinary skill in the art would reasonably have expected success in combining the ingredients because the prior art explicitly suggests administering them at the same time to the same subject. Combining two prior art active agents known to be useful when co-administered is well within the ordinary and routine level of skill in the art.

With respect to the term “orally administered,” the glucans of Yan et al. fulfill this limitation because they are suitable to be administered orally, even if this property is not explicitly disclosed by Yan et al. However, assuming for the sake of argument that the compositions used by Yan et al. are not orally administrable, making orally administrable compositions would be obvious to one of ordinary skill in the art in view of Donzis et al.

Donzis et al. discloses a solubilized glucan composition. (column 1 lines 28-33) This composition can be administered orally to a subject. (column 1 lines 34-40) Beta glucans that can be prepared in this manner preferably include yeast cell wall beta glucans. (column 1 lines 60-67) The glucans are solubilized in a solution of sorbitol. (column 2 lines 1-27) It is noted that this patent is referenced on p. 12, line 21 of the instant specification as being a method of producing a soluble yeast glucan suitable for oral administration. Therefore the glucans certainly fall within the limitations recited in instant claim 14.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use yeast beta glucans having been solubilized and prepared for oral administration by the method of Donzis et al. in the method of Yan et al. One of ordinary skill in the art would have been motivated to prepare the glucans in this manner because Donzis et al. already discloses that the method can be used to make orally administrable pharmaceutical preparations of glucan. One of ordinary skill in the art would reasonably have expected success because preparing a known pharmaceutical

agent for administration by a well known pathway, for example oral administration, is well within the ordinary and routine level of skill in the art.

Therefore the invention taken as a whole is *prima faice* obvious.

Response to arguments: Applicant's arguments, submitted May 13, 2008, have been fully considered as they relate to this ground for rejection and not found to be persuasive to remove the rejection. Applicant argues that there would be no expectation in the prior art for the oral administration of beta glucans to be successful at enhancing the effect of antibodies. However, determining the optimal route of administration of a known therapeutic agent is, as discussed above, a completely routine procedure that would not present any difficulty to one of ordinary skill in the art. Such experimentation would be undertaken as a matter of course in the development of any therapeutic agent for which oral administration would be desired. Therefore the rejection is deemed proper and maintained.

Because Applicant's amendment necessitated this new ground of rejection the rejection is made **FINAL**.

Conclusion

No claims are allowed in this application.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S Olson/
Examiner, Art Unit 1623
8/5/2008

/Shaojia Anna Jiang, Ph.D./
Supervisory Patent Examiner, Art Unit 1623